IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF TEXAS

PUBLIC HEALTH AND MEDICAL PROFESSIONALS FOR TRANSPARENCY, Plaintiff, v. UNITED STATES FOOD AND DRUG ADMINISTRATION, Defendant.	)	Civil Action No. 4:21-cv-01058-P

DEFENDANT'S BRIEF IN ADVANCE OF SCHEDULING CONFERENCE

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Pursuant to the Court's Order of November 18, 2021, ECF No. 21, Defendant, the U.S. Food and Drug Administration ("FDA"), respectfully submits this brief and attached appendix to assist the Court in setting a schedule for the processing of records responsive to Plaintiff's Freedom of Information Act ("FOIA") request.

LEGAL BACKGROUND

The Freedom of Information Act provides that any person has a right to obtain access to federal agency records subject to the Act, except to the extent that any portions of such records are protected from public disclosure by one or more of nine exemptions listed in the Act. *See* 5 U.S.C. § 552 (a)(3), (a)(4)(B), (b), (c); *see also Dep't of Air Force v. Rose*, 425 U.S. 352, 362–65 (1976) (stating that FOIA "assure[s] public access to all governmental records whose disclosure would not significantly harm specific governmental interests"). Under FOIA, a person may submit a request to a federal agency "reasonably decrib[ing]" records that s/he seeks to obtain. 5 U.S.C. § 552(a)(3)(A). An agency that has received a FOIA request is required, as relevant here, to "determine within 20 days (excepting Saturdays, Sundays, and legal public holidays) after the receipt of any such request whether to comply with such request." *Id.* § 552(a)(6)(A)(i). FOIA further provides that a requester "shall be deemed to have exhausted his administrative remedies with respect to such request if the agency fails to comply with the applicable time limit provisions." *Id.* § 552(a)(6)(C)(i).

FOIA's 20-working-day time period does not create a deadline for production. *Citizens for Responsibility & Ethics in Wash. v. FEC*, 711 F.3d 180, 189–90 (D.C. Cir. 2013).[1] Rather, "if the agency does not adhere to FOIA's explicit timelines, the 'penalty' is that the agency cannot rely on the administrative exhaustion requirement to keep cases from getting into court."

[1] Courts often rely on case law concerning FOIA from the D.C. Circuit, as it is "the federal appellate court with the most experience in this field." *Cooper Cameron Corp. v. U.S. Dep't of Labor*, 280 F.3d 539, 543 (5th Cir. 2002).

Id. No other provision in FOIA creates a specific timeframe for the release of records. *See* 5 U.S.C. §§ 552(a)(3)(A) (an agency shall make records responsive to a proper request "promptly available"), (a)(6)(C)(i) (same for litigated cases).

Indeed, the time required to process a FOIA request will inherently depend on the scope of the request and the nature of the information the requested records contain. Federal law generally prohibits the release of certain types of information, such as trade secrets and personal medical information. *See* 21 U.S.C. § 331(j); 18 U.S.C. § 1905; 21 C.F.R. §§ 20.61, 20.63. Consistent with these obligations to protect sensitive information, FOIA exempts several types of information from its production requirements. 5 U.S.C. § 552(b); *see Food Mktg. Inst. v. Argus Leader Media*, 139 S. Ct. 2356, 2366 (2019) ("FOIA expressly recognizes that 'important interests [are] served by [its] exemptions,' and '[t]hose exemptions are as much a part of [FOIA's] purpose[s and policies] as the [statute's disclosure] requirement.'" (brackets in original) (quoting *FBI v. Abramson*, 456 U.S. 615, 630–631 (1982); *Encino Motorcars, LLC v. Navarro*, 138 S. Ct. 1134, 1142 (2018))). As particularly relevant to this case, FOIA Exemption 4 permits withholding of "trade secrets and commercial or financial information obtained from a person and [that are] privileged or confidential.'" 5 U.S.C. § 552(b)(4). And Exemption 6 permits agencies to withhold or redact "personnel and medical files and similar files the disclosure of which would constitute a clearly unwarranted invasion of personal privacy." 5 U.S.C. § 552(b)(6). To ensure protection of this information and other information that is exempt from disclosure under FOIA, government agencies must carefully review all records and redact exempt information before the records are released to the FOIA requester. *See Daily Caller v. Dep't of State*, 152 F. Supp. 3d 1, 14 (D.D.C. 2015) (stating that the government has a

"responsibility" when processing FOIA requests to "safeguard[] potentially sensitive information").

FACTUAL BACKGROUND

I. Plaintiff's FOIA Request

On August 27, 2021, FDA received a FOIA request from Plaintiff seeking "all data and information for the Pfizer Vaccine enumerated in 21 C.F.R. § 601.51(e) with the exception of publicly available reports on the Vaccine Adverse Events Reporting System." Ex. A (Decl. of Suzann Burk) ¶ 24 (hereinafter "Burk Decl.") (App011).[2] Because the regulation cited by Plaintiff, 21 C.F.R. § 601.51, addresses "data and information in applications for biologics licenses," FDA interpreted Plaintiff's FOIA request as a request for all publicly releasable information in the original biologics license application ("BLA") submitted by BioNTech-Pfizer for the Comirnaty vaccine with internal file number STN 125742/0/0 ("original Comirnaty BLA"). *Id.* ¶ 25 (App011–12).

Based on FDA's initial assessment of the number of records potentially responsive to Plaintiff's FOIA request, FDA determined that the original Comirnaty BLA requested by Plaintiff comprises more than 329,000 pages of records. *Id.* (App012). In addition to those 329,000 pages, the original Comirnaty BLA includes data files in a format similar to a spreadsheet for which a page count cannot readily be determined. *Id.* (App012). FDA has assessed that the original Comirnaty BLA contains at least 126 of these data files. *Id.* (App012). Many of those data files themselves are very large, containing dozens of columns and over ten thousand rows of data. *Id.* (App012).

[2] Pursuant to this Court's Motion Practice standard II.C., the portions of the appendix relied upon are underlined.

II. The Parties' Negotiations Concerning a Processing Schedule

After Plaintiff filed its Complaint, ECF No. 1, and FDA filed its answer, ECF No. 14, the parties engaged in negotiations concerning a schedule for the processing and production of the non-exempt portions of records responsive to Plaintiff's FOIA request.[3]

To assist in negotiations and to assist Plaintiff in prioritizing certain records for processing and production, FDA provided two lists to Plaintiff revealing the (non-confidential) titles of sections of the original Comirnaty BLA. Burk Decl. ¶ 26 (App013). Those two lists, which served as something analogous to an index to certain sections of the original biological license application, totaled nearly 90 pages. *Id.* (App013). Where feasible and as a courtesy, FDA also annotated portions of the longer list (hereinafter, the "Index") with approximate page counts per section of the original Comirnaty BLA to assist Plaintiff in identifying documents for priority processing. *See* Ex. B (Index) (App022–108).

Once subsequent discussions revealed that Plaintiff was most interested in Section 5.2 of the original Comirnaty BLA and the raw data contained in Section 5.3 of the original Comirnaty BLA, FDA searched its system for those sections to evaluate their size and scope. Burk Decl. ¶ 26 (App013). FDA assessed that Sections 5.2 and 5.3 comprise more than 321,000 pages of records (plus additional data files) and requested that Plaintiff use the provided Index to prioritize the production of certain records. *Id.* (App013).

III. Plaintiff's Priority List

On November 4, 2021, Plaintiff provided FDA with the below list of records they requested FDA prioritize for processing ("Plaintiff's Priority List") in order of priority:

1. CRFs for site 1055 (from page 27 of the provided Index)

[3] These negotiations were described in detail in the parties' two joint reports. *See* ECF Nos. 18, 20. Only the negotiations relevant to FDA's current processing proposal are repeated in this filing.

2. CRFs for site 1081 (from page 31 of the provided Index)

3. CRFs for site 1096 (from page 38 of the provided Index)

4. CRFs for site 1128 (from page 46 of the provided Index)

5. Program Files/SAS files. Plaintiff requested 3 to 4 SAS files as a sample, in the first instance, so that it could assess whether it would like to prioritize the complete universe of SAS files. (from page 10 of the provided Index)

6. Section 5.2 of the original Comirnaty BLA – Tabular Listing of all Clinical Studies (from page 1 of the provided Index)

7. Section 4 of the original Comirnaty BLA – Nonclinical Study Reports (from page 1 of the provided Index)

8. Section 5.3.6 of the original Comirnaty BLA – Reports of Postmarketing Experience (from page 2 of the provided Index)

9. Section 16.1.1 of the original Comirnaty BLA – Protocol and/or Amendment, and specifically, Final Analysis Interim Independent Oversight Committees (from page 3 of the provided Index)

10. In the Analysis Datasets (ADaM) Section -- the Analysis Data Reviewers Guide, Analysis Dataset Definition, and Analysis Dataset Definition Stylesheet (from page 6 of the provided Index)

11. Tabulation Datasets (from page 11 of the provided Index)

12. CRFs for site 1085 (from page 33 of the provided Index)

Ex. C (Emails from Aaron Siri to Courtney Enlow) (Nov. 4, 2021)) (App122). Government counsel proposed that FDA process certain documents on Plaintiff's priority list by November 17 and December 1, 2021, with the parties to confer after December 1 regarding future productions. Plaintiff rejected that proposal.

IV. FDA's Productions of Records to Plaintiff

Although Plaintiff rejected FDA's production proposal, FDA nevertheless has been working to process and produce the non-exempt portions of records from Plaintiff's Priority List. FDA completed its proposed November 17 and December 1 productions. Burk Decl. ¶ 27 (App013–14). Specifically, on November 17, 2021, FDA produced all publicly releasable

information from the following:

- A portion of Plaintiff's priority item #5:
    - One .txt file; and
    - One SAS (data) file;[4]
- A portion of Plaintiff's priority item #6:
    - From Section 5.2 of the original Comirnaty BLA: The Tabular Listing;
    - From Section 5.2 of the original Comirnaty BLA: The Listing of Clinical Sites;
- Plaintiff's priority item #8:
    - From Section 5.3.6 of the original Comirnaty BLA: The Reports of Postmarketing Experience.

Id. (App013–14). This production amounted to 91 pages of records, as well as the two data files (the .txt and SAS files). FDA redacted material from the 91 pages under FOIA Exemptions 4 and 6 to protect the disclosure of trade secrets and commercial or financial information that was obtained from a person outside the government and that is privileged or confidential and to protect personal privacy. Because FDA assessed that there was no exempt material in the data files included in this production, FDA made no deletions or redactions to those files.

On December 1, 2021, FDA made a second release. Burk Decl. ¶ 27 (App014–15). Specifically, FDA produced publicly releasable information from the remainder of Section 5.2 of the original Comirnaty BLA to Plaintiff, making redactions under FOIA Exemption 6 to protect personal privacy. With this 248-page production, FDA completed processing and production of item 6 on Plaintiff's Priority List. Thus, as of the time of this filing, FDA has produced to

[4] In communications between FDA and Plaintiff, Plaintiff indicated that it was interested in obtaining "sample" SAS files, but none of the files Plaintiff identified in its priority list was an SAS file. Instead, Plaintiff identified .txt files that included "SAS" in their file names. In an attempt to provide Plaintiff with the information it requested, FDA produced one of the .txt files Plaintiff requested, as well as one xpt (SAS) file even though Plaintiff did not specifically prioritize any SAS files in its priority list. As a result, FDA's November 17, 2021, production included more records than FDA initially proposed. Burk Decl. ¶ 27 n.5 (App013).

Plaintiff the non-exempt portions of 339 pages, as well as two data files, and has completed processing and production of two items on Plaintiff's Priority List (items 6 and 8).

V. FDA's Upcoming Production of Records to Plaintiff

Since the time the parties filed their Second Joint Report, ECF No. 20, FDA has had an opportunity to assess the amount of time it will take to review additional records on Plaintiff's Priority List and has determined that it can complete processing of certain records at a pace faster than the previously proposed 500-pages-per-month rate.[5] *See* Burk Decl. ¶¶ 27–29 (App014–16). Accordingly, by December 13, 2021, FDA anticipates producing publicly releasable information from the following:

- All documents related to Plaintiff's priority item #1 – CRF files for site 1055 (approximately 2,030 pages);
- All remaining documents related to Plaintiff's priority item #5 –
    - Four additional .txt files that were listed on page 10 of the Index;
    - Four additional SAS files (not specifically listed on Plaintiff's priority list, but Plaintiff has expressed interest in these files during the course of negotiations).
- Publicly releasable information from the following additional sections of the original Comirnaty BLA:
    - Section 2.5 – Clinical Overview (approximately 333 pages)
    - Section 2.7.3 – Summary of Clinical Efficacy (approximately 182 pages)
    - Section 2.7.4 – Summary of Clinical Safety (approximately 344 pages)

Id. ¶ 27 (App014–15).

Thus, by the time of the Court's status conference on December 14, 2021, FDA anticipates that it will have produced to Plaintiff more than 3,000 pages of responsive materials,

[5] In light of FDA's assessment, on December 1, 2021, undersigned counsel informed Plaintiff's counsel of FDA's updated proposed processing schedule (as set forth here and below) and asked if Plaintiff would be amenable to the proposed schedule. As of the time of this filing, Plaintiff has not indicated whether it would accept this proposal.

most of which were listed on Plaintiff's Priority List. *Id.* (App015). Moreover, FDA will have completed processing and production of four items on Plaintiff's Priority List (items 1, 5, 6, and 8). *Id.* (App013–15).

FDA'S UPDATED PROPOSAL FOR A PROCESSING SCHEDULE

In addition to the December 13 production, FDA expects to be able to produce the next three items on Plaintiff's Priority List (items 2, 3, and 4) before the end of January 2022. Burk Decl. ¶ 28 (App015–16). FDA proposes to produce the below records to Plaintiffs according to the following schedule:

- **Thursday, December 30, 2021**: FDA proposes to produce publicly releasable information from Plaintiff's priority item #2 – CRF files for site 1081 (approximately 3,380 pages);
- **Tuesday, January 18, 2022**: FDA proposes to produce publicly releasable information from Plaintiff's priority item #3 – CRF files for site 1096 (approximately 2,937 pages); and
- **Monday, January 31, 2022**: FDA proposes to produce publicly releasable information from Plaintiff's priority item #4 – CRF files for site 1128 (approximately 3,452 pages).

Id. (App015).

If the Court adopts this schedule, by the end of January 2022, FDA will have produced publicly releasable information from more than **12,000 pages** of records and 10 unpaginated .txt or SAS data files. *Id.* (App015). Moreover, FDA will have completed production of seven of the first eight items on Plaintiff's Priority List (items 1, 2, 3, 4, 5, 6, and 8). *Id.* (App015–16).

Because FDA has not yet had an opportunity to assess the amount of time it will take to process other records responsive to Plaintiff's FOIA request, following the January 31, 2022 production, FDA proposes to make one production at the end of each subsequent month totaling

a minimum of 500 pages.[6] *Id.* ¶ 29 (App016). FDA's general estimate is that it takes approximately 8 minutes per page to review records for a FOIA production. *Id.* ¶¶ 18, 29 (App007, App016). It is difficult for FDA to know whether records will take more or less than the estimated eight minutes per page until reviewers have had an opportunity to perform at least a preliminary review of those records. *Id.* ¶¶ 18, 29 (App007–08, App016). Certain records will likely include more confidential information, and thus more corresponding redactions, which will require more research and production time. *Id.* ¶¶ 18, 29 (App007, App016). Once FDA has an opportunity to assess processing times for other records responsive to Plaintiff's FOIA request, FDA may be able to process and produce the non-exempt portions of records to Plaintiff at a rate faster than 500 pages per month. *Id.* ¶ 29 (App016). Thus, although FDA proposes a minimum rate of 500 pages a month after the January 31, 2022 production, FDA will produce records at a faster rate where feasible. *Id.* (App016).

ARGUMENT

FDA's Processing Schedule is Reasonable and Fair to All Requesters

As demonstrated below, the Court should adopt FDA's proposed schedule because it properly balances the interest of Plaintiff in receiving records responsive to its FOIA request with the interests of the vaccine sponsor in the protection of its confidential information, the interests of clinical trial participants in the protection of their personal privacy information, and the interests of other FOIA requesters whose requests are being processed alongside Plaintiff's. The proposed schedule is also feasible for FDA to complete with its limited processing resources and is not only consistent with processing schedules entered by other courts, but would in fact

[6] For purposes of calculating a "page count" of data records that are not paginated, FDA proposes considering twenty lines of spreadsheet data the equivalent of one page. For example, production of a spreadsheet containing 2,000 lines of data would be counted the equivalent of a 100-page PDF record.

result in the FDA producing records to Plaintiff at a rate much faster than most courts order.

First, FDA's proposed schedule properly addresses the interest of Plaintiff in receiving records because the schedule would result in production of the non-exempt portions of more than 12,000 pages of records and 10 unpaginated .txt or SAS data files to Plaintiff in less than two months from the date of the scheduling conference. Burk Decl. ¶ 28 (App015). Moreover, this schedule would result in the expedited production of seven of the twelve items on Plaintiff's Priority List (items 1, 2, 3, 4, 5, 6, and 8). *Id.* (App015–16).

In addition, FDA's proposed schedule provides FDA adequate time to assess whether records contain material that is exempt from production under FOIA and redact that exempt information. Plaintiff has requested records that comprise information submitted by the vaccine sponsor (Pfizer-BioNTech) to FDA. *Id.* ¶ 24 (App011). From FDA's experience with other similar FOIA requests, such records can be expected to contain both confidential business and trade secret information of Pfizer or BioNTech and personal privacy information of patients who participated in clinical trials. *Id.* ¶ 36 (App019–20). FDA is required to protect certain information under the law and this type of information is exempt from production under the FOIA. *See* 5 U.S.C. § 552(b)(4), (b)(6); *F.B.I. v. Abramson*, 456 U.S. 615, 621 (1982) ("Congress realized that legitimate governmental and private interests could be harmed by release of certain types of information and provided nine specific exemptions under which disclosure could be refused."); *see also* Burk Decl. ¶ 9 (App004). To ensure protection of this information, and other information subject to withholding under the FOIA exemptions, FDA must carefully review and, if necessary, redact exempt information on a line-by-line basis. *See* Burk Decl. ¶¶ 11, 13, 34 (App005, App006, App0018–19); *see also Daily Caller*, 152 F. Supp. 3d at 14. Moreover, if FDA determines not to withhold information that might be confidential

commercial information, it is sometimes required by regulation to provide notice to the company that submitted the information and an opportunity to file a claim for injunctive relief (a "reverse FOIA" claim). *See, e.g.*, 21 C.F.R. §§ 20.47, 20.48, 20.61(e).

FDA has assessed it can conduct this necessary review at a faster rate than normal for the 12,000 pages and 10 data files that comprise FDA's proposed productions through January 31, 2022. Burk Decl. ¶ 28 (App015). But FDA has not yet had a chance to make an assessment concerning the time it will take to review records after the proposed January 31, 2022 production. *Id.* ¶ 29 (App016). FDA is therefore relying on its standard rate of 8 minutes per page for review to propose a processing rate of 500 pages per month for subsequent productions. *Id.* (App016).

Furthermore, FDA's proposed schedule adequately protects the interests of other FOIA requesters. FDA, and specifically, the Center for Biologics Evaluation and Research ("CBER"), which maintains the records requested by Plaintiff, has 459 pending FOIA requests. *Id.* ¶ 22 (App010). Of the 459 requests pending before CBER, approximately 329 were received before Plaintiff's. *Id.* ¶ 22 (App010). Many of these new requests, including the request at issue in this case, have sought large amounts of data that require significant resources to process. *Id.* ¶ 21 (App009). The branch responsible for processing FOIA requests for CBER-maintained documents, CBER's Access Litigation and Freedom of Information Branch, has ten staff members – one branch chief and nine full-time staff members.[7] *Id.* ¶¶ 4, 31, 35 (App003, App007, App019). Two of those members began working for the office within the last four months and, because they are new staff members, they are not yet able to review records at the same rate as more experienced staff members. *Id.* ¶ 31 n.7 (App017).

[7] Along with processing FOIA requests, these ten staff members are also responsible for helping to address non-FOIA litigation-related document requests.

FDA is not able to commit to processing Plaintiff's request at a faster rate than the 12,000 pages and 10 data files by January 31, 2022, and 500 pages per month thereafter, without diverting significant resources away from the processing of other FOIA requests that are also in litigation, requests that are ahead of Plaintiff's in CBER's processing queues, as well as other non-FOIA record requests (such as, for example, document review to respond to discovery requests and third-party subpoenas). *Id.* ¶¶ 5, 8, 17, 36 (App003, App004, App007, App019–20). Such diversion would adversely impact FDA's ability to meet stipulated document processing deadlines and would be fundamentally unfair to other FOIA requesters, the majority of whom submitted their FOIA requests before Plaintiff and who likely believe, as Plaintiff does, that their FOIA request is important and needs to be processed expeditiously. *See id.* ¶ 22 (App010–11); *see also Elec. Privacy Info. Ctr. v. Dep't of Justice*, 15 F. Supp. 3d 32, 47 (D.D.C. 2014) (denying motion for preliminary injunction requesting immediate production of documents pursuant to FOIA request and noting that allowing the plaintiff "to jump to the head of the line would upset the agency's processes and be detrimental to the other expedited requesters"); *Daily Caller*, 152 F. Supp. 3d at 14 (stating that "the plaintiff's effort to jump to the head of the FOIA processing line would work a significant burden on both the agency and numerous interested parties").

Finally, FDA's proposed schedule that will result in production of the non-exempt portions of more than 12,000 pages and 10 data files by January 31, 2022, and 500 pages per month thereafter, Burk Decl. ¶ 28 (App015–16), is a processing rate that is much faster than other courts have ordered. As the D.C. Circuit has recognized, an agency's policy of processing 500 pages per request per month "serves to promote efficient responses to a larger number of requesters." *Nat'l Sec. Counselors v. Dep't of Justice*, 848 F.3d 467, 471–72 (D.C. Cir. 2017).

Numerous other courts have entered processing schedules requiring production of the non-exempt portions of 500 pages per month. *See, e.g.*, *Blakeney v. FBI*, No. 17-cv-2288 (BAH), 2019 WL 450678, at *2 (D.D.C. Feb. 5, 2019); *Republican Nat'l Comm. v. Dep't of State*, No. 16-cv-486, 2016 WL 9244625, at *1 (D.D.C. Sept. 16, 2016); *Color of Change v. Dep't of Homeland Sec.*, 325 F. Supp. 3d 447, 451 (S.D.N.Y. 2018); *Davis v. Dep't of Homeland Sec.*, No. 11-cv-203 (ARR) (VMS), 2013 WL 3288418, at *1 (E.D.N.Y. June 27, 2013). Courts do not waiver from the standard 500 page per month processing rate even when a FOIA request would take significant time to process. *See, e.g.*, *Colbert v. FBI*, No. 16-CV-1790 (DLF), 2018 WL 6299966, at *3 (D.D.C. Sept. 3, 2018) (permitting a processing rate of 500 pages per month for 71,000 responsive records).

In sum, FDA's proposed processing schedule is fair to Plaintiff. It results in the non-exempt portions of 12,000 pages and 10 data files produced to Plaintiff in less than 60 days and accommodates Plaintiff's request to prioritize production of numerous records. Burk Decl. ¶ 28 (App015–16). It is fair to the vaccine sponsor and individuals who participated in clinical trials, as the schedule allows FDA adequate time to review the records for confidential commercial information and information that would result in an unwarranted invasion of personal privacy. *Id.* ¶ 36 (App019–20). And it is fair to other FOIA requesters, who should not be prejudiced merely because Plaintiff has the resources to file a lawsuit in an attempt to obtain a faster processing schedule. *Id.* (App019–20).

CONCLUSION

For the foregoing reasons, Defendant respectfully requests that the Court enter FDA's proposed processing schedule.

Dated: December 6, 2021

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on December 6, 2021, I electronically transmitted the foregoing to the parties and the clerk of court for the United States District Court for the Northern District of Texas using the CM/ECF filing system.

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